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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Sterzer et al.
Serial No.: 10/822,367
Filed: April 12, 2004
Title: INFLATABLE BALLOON CATHETER STRUCTURAL DESIGNS AND METHODS FOR TREATING DISEASED TISSUE OF A PATIENT
Art Unit: 3739
Examiner: Rosiland Stacie Rollins

APPEAL BRIEF COVER LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-14501

Sir:

In response to the "NOTIFICATION OF NON-COMPLIANT APPEAL BRIEF" of January 5, 2007, please substitute the enclosed Applicant's Appeal Brief (in triplicate), which does comply with the requirements of 37 CFR 1.41.37(c), for the original non-compliant Applicant's Appeal Brief filed in triplicate on November 24, 2006.

Respectfully submitted,

George J. Seligsohn

Attorney for Applicant
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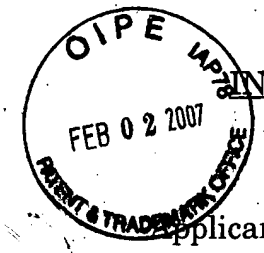

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Before the Board of Patent Appeals and Interferences

Applicant: Sterzer et al. Appeal No.
Serial No.: 10/822,367
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Title: INFLATABLE BALLOON CATHETER STRUCTURAL DESIGNS AND METHODS FOR TREATING DISEASED TISSUE OF A PATIENT
Art Unit: 3739
Examiner: Rosiland Stacie Rollins

APPLICANT'S APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-14501

Sir:

Each of the following nine (9) items, being set forth in order, of this Appeal Brief (being filed in triplicate) is in accordance of the requirements of 37 CFR 41.37(c):

37 CFR 41.37(c)(1)(i)

REAL PARTY IN INTEREST

The real party in interest is MMTC, Inc., which is the assignee of an assignment recorded in the Patent and Trademark Office. Assignor and co-applicant Fred Sterzer is the president and principal stockholder of MMTC. Inc. Assignor and co-applicant Daniel D. Mawhinney is a stockholder of MMTC.

37 CFR 41.37(c)(1)(ii)

RELATED APPEALS AND IINTERFERENCES

There are no related appeals and interferences.

37 CFR 41.37(c)(1)(iii)

STATEMEENT OF STATUS OFF ALL CLAIMS

There were originally 17 claims in this application, 16 of which are being appealed. Independent Claim 1, as amended by the amendment filed October 1, 2004, is being appealed. Each of original Claims 2-8, dependent on amended Claim 1, is being appealed. Independent Claim 9, as amended by the amendment filed October 1, 2004, is being appealed. Each of original Claims 10, 11 and 17, dependent on amended Claim 9, is being appealed. Claim 12, dependent on amended Claim 9, was cancelled by the by the amendment filed November 18, 2005. Each of original Claims 13-16, now dependent on Claim 11, is being appealed.

37 CFR 41.37(c)(1)(iv)

AMENDMENT FILED SUBSEQUENT TO FINAL REJECTION

No amendment was filed subsequent to final rejection. However, a response subsequent to final rejection was filed on August 4.2006, which was ineffective, by the Examiner, in placing the claims in condition for allowance.

37 CFR 41.37(c)(1)(v)

SUMMARY OF THE INVENTION

Applicant's invention is directed to balloon catheter designs that incorporate an antenna cooperatively situated with respect to an external balloon surface for use in treating diseased tissue of a patient. The respective teachings of prior-art United States patent application 10/337,159 (now US patent 6,847.848 B2) and United States patents 5,007,437, 5,992,419 and 4,190,053 (page 1, line 21 to page 2, line 18) are incorporated by reference. FIGURE 1 (described page 3, line 25 to page 4, line 6) shows an example of a typical microwave prior-art balloon catheter design for treating diseased prostate tissue of a patient. This catheter design, in use, includes an internal antenna situated within an inflated balloon in which the antenna is separated from the exterior surface of the balloon pressing the urethral tissue proximate to the diseased prostate tissue by the balloon-inflating fluid (e.g. water). FIGURS 2a, 2b and 2c (described on page 4, line 7 to page 5, line 19) show an experimental embodiment of applicant's invention that employs a directional spiral antenna situated on the external surface of a longitudinally-split silicone-rubber tube that surrounds the catheter balloon. FIGURS 3a, 3b, 4a, 4b, 5a and 5b (described on page 5, line 20 to page 6, line 29) show a first preferred embodiment of the present invention which, like the experimental embodiment of FIGURS 2a, 2b and 2c, also employs a directional spiral antenna situated on the external surface of a longitudinally-split silicone-rubber tube that surrounds the catheter balloon. In addition, this first preferred embodiment employs an inlet lumen to transport a coolant fluid (either a gas or preferentially a liquid, such as water having a high heat capacity) to fill and thereby inflate the catheter balloon and an outlet lumen to extract coolant fluid from the catheter balloon. For cooling purposes, the coolant fluid may be continuously pumped through the catheter balloon. FIGURE 6 (described on page 6, line 30 to page 10, line 30) shows the use of this first preferred embodiment in the treatment of diseased prostate tissue, such as malignant tumor tissue within non-diseased prostate tissue or Benign Prostatic Hypertrophy (BPH). The directional spiral antenna, which is situated in cooperative relationship with the exterior surface of a coolant-fluid

inflated catheter balloon, is in direct and intimate contact with the utheral lining tissue overlying the non-diseased prostate tissue located closest to the diseased malignant tumor tissue. This arrangement causes the pattern of the microwave radiation transmitted from the external directional antenna and directed toward the malignant tumor tissue to be spatially confined to and effect only the desired heating of the targeted malignant tumor tissue and the undesired heating of the intervening healthy prostate tissue, as well as the lining tissue of urethra. The undesired heating of the intervening healthy prostate tissue and lining tissue of urethra is limited to a maximum safe temperature of 42°C by the continuously-flowing, high heat capacity coolant fluid (e.g. water), while a multi-frequency microwave radiometer continuously measures the temperature of the heated tissues. Further, this continuously-measured temperature by the multi-frequency microwave radiometer may be both fed back to the microwave power generator to control the power output thereof supplied to the radiating antenna and to control the amount of coolant fluid cooling. This makes it feasible to minimize the amount of microwave power needed, while maximizing the proportion of the radiation absorbed by the targeted tumor tissue and minimizing the proportion of the radiation absorbed by all of the intervening substance between the radiating antenna and the targeted tumor tissue. In the case of FIGURE 6, where external directional antenna is in direct contact with the lining tissue of urethra, the intervening substance is confined to only the lining tissue of urethra and the healthy prostate tissue. Further, by also measuring the surface temperature of the urethral lining tissue, a computer can use readings of the surface and radiometric temperatures to control both the amount of microwave heating and surface cooling in order to generate the desired optimum temperature distributions. In particular, the depth of heating is controlled by providing colder surface temperatures, which results in more power being delivered to the underlying diseased tissue (e.g., prostate malignant tumor tissue) without damaging the surface tissues. Thus, the deeper will be the depth of heating of the underlying diseased tissue. In particular, overheating of the sphincters of the urethra, with consequent damage thereto is avoided by such spatially-

localized heating of targeted diseased prostate tissue (e.g. prostate cancer lesions or BPH) to a temperature high enough to cause ablation thereof or to cause the urethral tissue lining the prostate to form a "biological stent" " (disclosed in prior-art United States patent 5,992,419) in the urethra because the tissue surrounding the urethra can be safely raised to higher temperatures than is safely possible with conventional balloon catheters. FIGURES 7a and 7b (described on page 10, line 23 to page 11, line 25) shows a second preferred embodiment of the present invention that comprises (1) a helical omnidirectional monopole antenna situated in cooperative relationship with the exterior surface of the balloon of a balloon catheter and (2) coolant-fluid inlet and outlet lumens situated within the catheter. More specifically, the antenna constitutes metallic helical spring windings enveloping the exterior longitudinal surface of the balloon in a deflated state, with the most proximate winding of the spring being attached to the inner conductor of a microwave feedline thereto When the balloon is inflated, the spring tends to unwind under balloon pressure, thereby increasing its diameter so that it remains in proximity to the exterior surface of the balloon in its inflated state. Thereafter, when the balloon is deflated, the restoring force of the spring returns it to its neutral state. A balloon catheter incorporating an antenna having this helical omnidirectional configuration would be particularly suitable for use as an interstitial probe for treating sub-coetaneous diseased tissue of a patient, such as (1) deep-seated tumors and (2) varicose veins, as disclosed in the aforesaid prior-art United States patent application 10/,337,159. In addition to the first and second preferred embodiments of the present invention described above, the external antenna's configuration (page 11, line 26 to page 12, line 8) may comprise metallic printing directly on the exterior surface of the balloon. (In the case of a spiral microstrip configuration, the metallic ground plane would be directly printed on the internal surface of the balloon.)

balloon catheter incorporating
directional configuration would be particularly
interstitial probe for treating sub-coetaneous
deep-seated tumors
present invention described
(page 11, line 26 to page

37 CFR 41.37(c)(1)(vi)

GROUNDS OF REEJECTION FOR REVIEW

1. Claims 1 and 2 are rejected under 35 U.S.C. 102(a) as being anticipated by Truckai et al. (US 6813520) who disclose, in Figs. 2 and 3, a balloon catheter comprising a catheter body, an inflatable balloon surrounding the catheter body and an external antenna (14) situated outside of the balloon in a cooperative relationship with the external surface of the balloon.

2. Claims 1-10 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasevich et al. (US 5057106) in view of Truckai et al. for obviousness because Kasevich et al. discloses all elements of the claims including an external antenna situated outside the balloon (col. 5, line 37) and Truckai et al. discloses the antenna being in a cooperative relationship with the exterior surface of the balloon.

3. Claims 11 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasevich et al. (US 5057106) in view of Truckai et al. and further in view of Sterzer et al. (US 5688050) because Sterzer et al. discloses a radiometer and a single-pole two position switch to provide means for measuring the temperature of the patient to facilitate effective treatment.

37 CFR 41.37(c)(1)(vii)

APPLICANT'S ARGUMENTS

1. TRAVERSAL OF TRUCKAI ET AL. REJECTION OF CLAIMS 1 AND 2

The Examiner in her support of her rejection of independent amended Claim 1 under 35 U.S.C. 102(e) asserts that Truckai et al.'s array of electrodes 14 constitutes an "external antenna (14) situated outside of the balloon in a cooperative relationship with the external surface of the balloon (underlining added)." Applicant traverses this assertion. It is applicant's position that the array of electrodes 14 structure disclosed by Truckai et al. does not constitute an antenna structure, but, instead, constitutes a significantly different dielectric-heating structure.

As known in the art, the structure of an antenna is designed, in accordance with Maxwell's equations, to radiate a given spatial pattern of electromagnetic waves of a certain frequency situated within a given RF or microwave frequency band in response to electrical energy of this certain frequency being applied as an input thereto. The structure of the antenna includes one or more radiating elements having specified dimensions determined by the given RF or microwave frequency band and may or may not also include one or more reflector elements. The given spatial pattern is determined by the spatial configuration of the one or more elements.

As discussed in the above "Summary of the Invention," applicant's disclosed antenna is designed to radiate electromagnetic waves at a "microwave" frequency. In the case of applicant's Fig. 6, the frequency is stated to be within the 915 MHz band and should be varied until the best antenna match is determined by measuring the frequency at which the minimum amount of power is reflected and then operating at this optimum frequency. It is also stated that the antenna is an external directional antenna that causes the pattern of the transmitted microwave radiation pattern to be directed toward malignant tumor tissue.

On the other hand, in the case of applicant's Figs. 7a and 7b, the antenna is stated to be a helical omnidirectional monopole antenna

having a configuration that would be particularly suitable for use as an interstitial probe, for treating sub-coetaneous diseased tissue of a patient, such as (1) deep-seated tumors and (2) varicose veins.

Truckai et al. discloses structure for ablating target tissue (e.g., endometrial tissue) by applying RF power (e.g., 500 kHz 30W power) to an array of spaced electrodes 14 in contact with the target tissue to be ablated. The array of spaced electrodes 14 (See Truckai et al. Figs. 18, 19A-19C, Col. 7, lines 1-25 and Col. 10, line 48 to Col. 11. 13) do not have dimensions which makes them, in accordance with Maxwell's equations, capable of radiating a spatial pattern of electromagnetic waves, and, therefore, does not constitute an "antenna" structure. Instead, the array of spaced electrodes 14 constitutes a "dielectric-heating" structure.tion that would be partic

More particularly, if a D.C. voltage were applied across spaced electrodes separated by a dielectric material having a high DC resistance, a small DC current would flow through the dielectric material, causing a relatively small amount of I^2R heating of the dielectric material. However, if an RF voltage (e.g., 500 kHz) is applied across the spaced electrodes and the dielectric material is a lossy dielectric material at RF (e.g., endometrial target tissue), a relatively large amount of dielectric heating of the dielectric material (which is a function of the magnitude of the RF voltage, the value of the RF frequency and the value of the loss factor) takes place. Specifically, the RF voltage across the spaced electrodes results in an RF electric field (not an RF electromagnetic field) that causes the center of gravity of the electrons of each atom of the lossy dielectric material to be moved in one direction with respect to the nucleus of that atom during a first half of each RF cycle and to be moved in the opposite direction atom during the second half of each RF cycle. It is this back-and forth oscillation during each RF cycle results in the relatively large amount of dielectric heating of the dielectric material.

From the foregoing discussion, it is clear that the RF electric energy field generated by the dielectric-heating structure taught by Truckai et al. operates only over the localized spatial region defined by the spaced electrodes of their array 14. Certainly, the dielectric-heating structure taught by Truckai et al. does not suggest the n RF electromagnetic field) that caus

of each atom of t

antenna structure defined in applicant's amended independent Claim 1, which is capable of radiating outward a field of electromagnetic waves. Therefore, the rejection of amended independent Claim 1 (and Claim 2 dependent thereon) under 35 U.S.C. 102(e) should be withdrawn.

37 CFR 41.37(c)(1)(vii)

APPLICANT'S ARGUMENTS

2.. TRAVERSAL OF KASEVICH IN VIEW OF TRUCKAI ET AL. REJECTION OF CLAIMS 1-10 AND 17

The admittedly old inflatable balloon catheter structure for use in treating diseased tissue of a patient defined in the preamble of independent amended Claim 1, written in Jepson form, includes an antenna which transmits radiant energy to diseased tissue thereby to effect the heating of the diseased tissue while an exterior surface of the inflated balloon is pressing the diseased tissue. The novelty clause of independent amended Claim 1 states that the antenna is longitudinally physically situated in cooperative relationship with the exterior surface of the balloon, thereby in use causing the inflated balloon pressing the diseased tissue to result in the antenna being in direct contact with irradiated tissue of the patient

In her rejection of independent amended Claim 1 under 35 U.S.C. 103(a), the Examiner relies on the structural teaching of Truckai et al. to meet the structural teaching of the antenna defined in the aforesaid novelty clause of independent amended Claim 1. However, as argued above, the structural teaching of Truckai et al. is directed to a dielectric-heating structure, rather than the antenna structure defined in the novelty clause of independent amended Claim 1. This is one reason for withdrawing the rejection of independent amended Claim 1 under 35 U.S.C. 103(a).

Another reason for withdrawing the rejection of independent amended Claim 1 under 35 U.S.C. 103(a) is that the respective teachings of Kasevich et al. and Truckai et al. teach away from one another, as well as from the teaching of the structure defined in independent amended Claim 1. Although structurally very different, both Truckai et al. and independent amended Claim 1 functionally teach treating diseased tissue of a patient by heating the diseased tissue with an inflated balloon in contact with the diseased tissue. In both Truckai et al. and independent amended Claim 1, the heated temperature may be high enough to cause ablation of the diseased tissue. However, Kasevich et al. functionally teach the use of

microwave balloon angioplasty to heat plaque (which is not tissue) in a blood vessel without heating wall tissue of the vessel.

More particularly, Kasevich et al. states, "The present invention relates in general to microwave balloon angioplasty, and pertains more particularly to a microwave or radiofrequency catheter system for the heating of plaque in arteries or blood vessel (Column 1, lines 14-17)." The disclosed intended use of all but the Fig.14 one of the various antenna configurations of Kasevich et al., in the treatment of coronary vessel plaque with microwave balloon angioplasty is "to deliver microwave energy to a specific layer of plaque without heating wall tissue during pressure application by the balloon (Column 5, lines 15-17)." Further, Kasevich et al. states, "In accordance with the present invention, there are now described a number of techniques for providing control of the quantity of microwave energy that is coupled to coronary vessel plaque without heating vessel tissue (Column 5, lines 27-31)." NOTE: the above-quoted sentence (2) is the first sentence in the Column 5, lines 27-37 paragraph which includes the phrase "outside the balloon" (relied on by the Examiner in rejecting amended Claim 1) on line 37 thereof. This Column 5, lines 27-37 paragraph occurs in Kasevich et al. prior to their description of any of the specific Figs. 1-36 of their drawing.

FIGURES 1, 3, 6 and 13 of Kasevich et al. show different configurations of an antenna situated inside the balloon and FIGURES 4 and 5 of Kasevich et al. show different configurations of an antenna situated between the balloon surfaces, but only FIGURES 11 and 14 of Kasevich et al. comprise antenna structures that extend outside of the balloon. In the case of FIGURE 11 (described on Column 9, lines 22-49), the antenna structure comprises (1) a guide wire passing through the entire length of the balloon and terminating in tip 92 situated outside the distal end of the balloon and (2) chokes A and B situated within the balloon, respectively, in the vicinity of the proximate and distal ends of thereof. This results in only the portion of the guide wire between chokes A and B inside the balloon operating as a radiator. Therefore, tip 92 of FIGURE 11 cannot be considered a radiator situated outside of the balloon. However, FIGURE 14 (described on Column 6, lines 3-16), which comprises an antenna extending through

the length of the balloon and terminating in a tip situated outside of the distal end of the balloon which has a ferrite layer thereon which is heated by microwave energy in the antenna, The heated ferrite at the antenna tip, with the balloon in a deflated state, may be used to melt, ablate and remove some plaque from a fully-blocked artery. Once some plaque has been removed, the balloon may be inflated and the microwave angioplasty carried out. Thus, the only one of the various antenna configurations of Kasevich et al. that includes an antenna configuration "outside the balloon" is shown in their FIGURE 14 (the structure of which may be modified as shown in FIGURE 27). Kasevich et al. state, "FIG. 14 shows the antenna A extending through the balloon B and having at its tip T a concentric layer of ferrite material that may have a Curie temperature in the 400°C-500°C range. Microwave energy is rapidly absorbed in the ferrite when this material is at a current maximum of the antenna. The primary function of this hot tip (when the ferrite is at the far end of the antenna) is to melt plaque (ablation). This is used for those cases where the artery is fully blocked by plaque, and it would therefore be necessary to remove some plaque in order to insert the balloon. In FIG. 14, note the plaque volume at V. Once some plaque has been removed, the balloon may be inflated and the microwave angioplasty carried out (Column 6, lines 3-16)." Kasevich et al. further state, "As indicated previously, FIG. 27 herein teaches the use of a lossy sleeve 80 for focused heating. An alternate embodiment is to employ two ferrite sleeves F1 and F2, as illustrated in FIG. 14, some distance apart along the antenna axis but outside of and essentially in front of the balloon. In this regard, the arrow A1 in FIG. 14 illustrates the direction of the insertion of the antenna structure." (Column 6, lines 17-23). Kasevich et al. still further state, "As indicated previously, FIG. 14 shows a two-ferrite geometry. The ferrites F1 and F2 hear through the plaque (occluded artery) using microwave frequency F1. To withdraw the antenna back through the plaque and avoid sticking, the ferrite F2 is tuned to a frequency F2. It remains hot to allow the antenna to be withdrawn prior to inserting the balloon and using the antenna in its normal plaque welding mode. Also, ferrite, hot tip antenna may be completely removed from the catheter in a different antenna design employed for

low temperature operation." (Column 6, lines 24-34). It is plain from the above-quoted statements of Kasevich et al. that the "outside the balloon" antenna configuration, shown in FIGURE 14 of Kasevich et al., does not structurally or functionally show, or even suggest, an inflatable balloon catheter design for treating diseased tissue of a patient, which incorporates an antenna which is longitudinally physically situated in cooperative relationship with the exterior surface of the balloon, thereby in use causing the inflated balloon pressing the diseased tissue to result in the antenna being in direct contact with irradiated tissue of the patient, as called for in amended Claim 1.

Thus, it is not rationally possible to combine the structurally and functionally oppositely-directed teachings of Kasevich et al. and Truckai et al. to meet the teaching of the invention defined in amended Claim 1. Therefore, the rejection of amended independent Claim 1 (and Claims 2-8 dependent thereon) under 35 U.S.C. 103a) should be withdrawn.

Further, it is not rationally possible to combine the structurally and functionally oppositely-directed teachings of Kasevich et al. and Truckai et al. to meet the teaching of the invention defined in amended independent Claim 9 (which is for use in heat treating diseased prostate tissue of a patient, but is otherwise similar in structure to that of amended independent Claim 1), together with Claim 10 dependent on amended independent Claim 9.

37 CFR 41.37(c)(1)(vii)

APPLICANT'S ARGUMENTS

3.. TRAVERSAL OF KASEVICH IN VIEW OF TRUCKAI ET AL. AND IN VIEW OF STERZER ET AL. REJECTION

Each of Claims 11 and 13-16, dependent on amended independent Claim 9, is believed allowable for at least the same reasons set forth above with respect to amended independent Claim 9 and amended independent Claim 1.

37 CFR 41.37(c)(1)(vii)

APPLICANT'S ARGUMENTS

4.. CONCLUSION

For all the reasons set forth above in Applicant's Argument, the Board of Patent Appeals and Interferences is respectfully urged to reverse the final rejection by the Examiner of (1) amended independent Claim 1 together with dependent Claim 2, under 35 U.S.C. 102(e) as anticipated by Truckai et al. (US 6,813,520); (2) amended independent Claim 1, together with dependent Claims 2-8, amended independent Claim 9 and dependent Claims 10 and 17 under 35 U.S.C. 103(a) as unpatentable over by Kasevich et al. (US 5057106) in view of Truckai et al.; and (3) dependent Claim 11, amended dependent Claim 13 and dependent Claims 14-16 under 35 U.S.C. 103(a) as anticipated by Kasevich et al. in view of Truckai et al. and further in view of Sterzer et al. (US 5688050), and allow each of these Claims 1-11 and 13-17.

Respectfully submitted,

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Appendix

37 CFR 41.37(c)(1)(viii)

APPEALED CLAIMS

1. In a balloon catheter suitable for use in treating diseased tissue of a patient, wherein said balloon catheter comprises a catheter body, an inflatable balloon surrounding said catheter body, and an antenna, wherein in use (1) said catheter with said balloon in a deflated state may first be positioned so that said antenna is aligned with said patient's diseased tissue and (2) said balloon may then be inflated so that an exterior surface of said balloon presses said diseased tissue while said antenna transmits radiant energy to said diseased tissue thereby to effect the heating of said diseased tissue; the improvement wherein:

said antenna is longitudinally physically situated in cooperative relationship with said exterior surface of said balloon, thereby in use causing said inflated balloon pressing said diseased tissue to result in said antenna being in direct contact with irradiated tissue of said patient.

2. The balloon catheter defined in Claim 1, wherein said catheter body comprises:

an input lumen that provides a first pathway for coolant fluid from a source situated outside of said balloon catheter to enter said balloon; and

an output lumen that provides a second pathway for said to leave said balloon and exit said balloon catheter.

3. The balloon catheter defined in Claim 1, wherein:

said external antenna is a directional antenna.

4. The balloon catheter defined in Claim 3, wherein:

said external directional antenna comprises a spiral microstrip structure.

5. The balloon catheter defined in Claim 4, wherein said spiral microstrip structure comprises:

longitudinally-split plastic tubing having an inner longitudinal surface thereof enveloping said longitudinal external surface of said balloon with a metallic ground plane portion of said external directional antenna directly attached to said inner longitudinal surface of said tubing and a metallic spiral portion of said external directional antenna directly attached to an outer longitudinal surface of said tubing.

6. The balloon catheter defined in Claim 1, wherein:

said external antenna is an omnidirectional antenna.

7. The balloon catheter defined in Claim 6, wherein:

said external omnidirectional antenna comprises a metallic helical structure surrounding said longitudinal external surface of said balloon.

8. The balloon catheter defined in Claim 1, wherein:

said external antenna is an external microwave antenna for transmitting microwave radiant energy to said diseased tissue while said balloon is inflated thereby to effect the heating of said diseased tissue.

9. In a system suitable for use in heat treating diseased prostate tissue of a patient, wherein said system comprises a balloon catheter including a catheter body, an inflatable balloon surrounding said catheter body, and an antenna; wherein in use (1) said catheter with said balloon in a deflated state may first be inserted into an orifice of said patient and positioned so that said antenna is aligned with said patient's prostate tissue and (2) said balloon may then be inflated so that an exterior surface of said balloon presses against lining tissue of said orifice that is adjacent to said patient's prostate tissue, the improvement wherein:

said antenna is a directional antenna that (1) is longitudinally physically situated in cooperative relationship with said exterior surface of said balloon, thereby in use causing said inflated balloon pressing against said lining tissue of said orifice that is adjacent to said patient's prostate tissue, to result in said antenna being in direct contact with said lining tissue of said patient and (2) transmits radiant energy of a given frequency band to said diseased prostate tissue in response to power within said given frequency band being supplied to said antenna; and

a power source and means including a feedline for supplying a given amount of power within said given frequency band to said external

directional antenna, thereby to irradiate said diseased tissue and thereby effect the heating to a given therapeutic temperature.

10. The system defined in Claim 9, wherein:

said given frequency band is the 915 MHz frequency band.

11. The system defined in Claim 9, wherein said system further comprises a radiometer, and wherein:

said means including a feedline further includes a single-pole two-position switch for forwarding said given amount of power within said given frequency band from said power source to said feedline when said single-pole two-position switch is in a first switch position thereof and for forwarding thermal radiation received by said external directional antenna and supplied to said feedline to said radiometer when said single-pole two-position switch is in a second switch position thereof;

whereby said radiometer provides a reading indicative of the temperature of said irradiated diseased tissue.

13. The system defined in Claim 11, wherein said balloon catheter comprises:

means for supplying said balloon's interior volume with a coolant fluid for removing heat from said lining tissue of said orifice thereby to maintain the temperature of said lining tissue of said orifice at a safe temperature.

14 . The system defined in Claim 13, wherein:

said safe temperature is no higher than 42°C.

15 . The system defined in Claim 13, wherein said balloon catheter comprises a catheter body surrounded by said balloon thereof, and said means for supplying said balloon's interior volume with a coolant fluid comprises:

an input lumen in said catheter body that provides a first pathway for coolant fluid from a source situated outside of said balloon catheter to enter said balloon; and

an output lumen in said catheter body that provides a second pathway for said to leave said balloon and exit said balloon catheter.

16. The system defined in Claim 15, wherein said orifice of said patient is said patient's urethra.

17. The system defined in Claim 9, wherein said orifice of said patient is said patient's urethra.

37 CFR 41.37(c)(1)(ix)

EVIDENCE SUBMITTED UNDER 37 CFR 1.130, 1.131, OR 1.131

NONE

37 CFR 41.37(c)(1)(x)

DECISIONS RENDERED BY A COURT OR THE BOARD

NONE

Respectfully submitted,

George J. Selitzsolun

Attorney for Applicant
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